

REMARKS/ARGUMENTS

Claims 1-20 are pending in the present application. In the Office Action, claims 1-3, 5-13 and 15-20 were rejected and claims 4 and 14 were withdrawn. In response to the Office Action, claims 1 and 11 have been amended. No new matter has been added. Reconsideration of the pending claims is respectfully requested.

Claim Rejections – 35 U.S.C. § 103

Chermoni in view of Fischell

Claims 1-2, 5-12, 15-18 and 20 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Chermoni (U.S. Patent Publication No. 2002/0156496) in view of Fischell et al. (U.S. Patent No. 5,639,274). Such rejection is overcome for at least the following reasons.

Independent claim 1 has been amended to recite in part an axially movable sheath disposed over at least part of the catheter shaft and the expandable member, the sheath having a reinforced distal portion adapted to resist radial expansion of the expandable member. Support for this amendment may be found in paragraph 0037 of the application as filed, therefore no new matter has been added. Claim 1 has also been amended to recite in part that moving the sheath axially toward the proximal end of the catheter shaft allows at least part of the expandable member to expand against the shuttle to cause the shuttle to radially expand while a remaining portion of the expandable member is constrained by the sheath, thus causing at least one of the plurality of stent segments to expand. Support for this amendment may be found in Figs. 6A-6D as well as paragraph 0043 of the application as filed, therefore no new matter has been added. Neither Chermoni nor Fischell teach or suggest these features of claim 1.

Chermoni discloses a catheter configured to carry one or more stents and having an inflatable balloon for expanding a stent surrounding the balloon (Abstract). The catheter also has a positioner for moving the one or more stents relative to the balloon from a first position in which the stent does not surround the balloon to a second position in which the stent surrounds the balloon (Abstract). Chermoni, however, fails to teach or suggest a sheath, as acknowledged

by the Examiner in the Office Action (page 3). Since Chermoni does not disclose a sheath, Chermoni fails to teach or suggest an axially movable sheath disposed over at least part of the catheter shaft and the expandable member, the sheath having a reinforced distal portion adapted to resist radial expansion of the expandable member, as now recited by amended claim 1. Similarly, due to the absence of a sheath in Chermoni, the cited reference also fails to teach or suggest that moving the sheath axially toward the proximal end of the catheter shaft allows at least part of the expandable member to expand against the shuttle to cause the shuttle to radially expand while a remaining portion of the expandable member is constrained by the sheath, thus causing at least one of the plurality of stent segments to expand, also now recited by amended claim 1.

Fischell fails to provide the elements missing from Chermoni. Fischell discloses an integrated catheter system including a stent catheter and a balloon angioplasty catheter (Abstract). The balloon angioplasty catheter has an inflatable balloon near the catheter's distal end which is initially used for dilation of a vessel (Abstract). The stent catheter has an outer tube with a stent containment cavity and the stent is displaced over the balloon (Abstract). The stent is held in place over the balloon and the outer tube is pulled back (Abstract) leaving the stent positioned over the balloon so that it may be radially expanded into the wall of the vessel (Abstract). During radial expansion of the stent, the outer tube is fully retracted such that no part of the balloon is constrained from expansion by the outer tube (see Figs. 7E-7F). Because the outer tube does not constrain the balloon, Fischell fails to teach or suggest that moving the sheath axially toward the proximal end of the catheter shaft allows at least part of the expandable member to expand against the shuttle to cause the shuttle to radially expand while a remaining portion of the expandable member is constrained by the sheath, thus causing at least one of the plurality of stent segments to expand, as recited by amended claim 1. In Fischell, whether the stent within the outer tube with just the balloon exposed, or with the stent positioned on the balloon, the entire balloon is inflated without constraint by the sheath. If a portion of the balloon were constrained by the outer tube while the stent is positioned on it, only a portion of the stent would be expanded, thereby preventing the stent from performing its function of scaffolding the diseased vessel, and potentially preventing the stent from being removed from the vessel due to

the partial expansion of its distal end. This phenomenon can be highly risky to the patient. Moreover, Fischell also fails to teach or suggest that the sheath has a reinforced distal portion adapted to resist radial expansion of the expandable member, as recited by amended claim 1. Because, as noted above, Fischell's device would fail to serve its intended purpose if the stent were partially expanded, no motivation or suggestion is provided for reinforcing a distal portion of the outer tube.

Because neither Chermoni or Fischell, alone or in combination teach or suggest each and every element of the claimed invention, *prima facie* obviousness cannot be established under 35 U.S.C. § 103(a). Applicants respectfully request withdrawal of the 35 U.S.C. § 103(a) rejection and allowance of independent claim 1 and the claims depending therefrom.

Independent claim 11 has been similarly amended as claim 1, therefore for at least the same reasons as discussed above with respect to claim 1, Applicants respectfully request withdrawal of the 35 U.S.C. § 103(a) rejection of claim 11 and allowance of claim 11 and the claims depending therefrom.

Chermoni in view of Fischell and Shaknovich

Claims 3 and 13 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Chermoni in view of Fischell (U.S. Patent No. 7,137,993) and further in view of Shaknovich (U.S. Patent No. 5,807,398). Such rejection is overcome for at least the following reasons.

Claim 3 includes the features recited in independent base claim 1 which has been amended to recite in part an axially movable sheath disposed over at least part of the catheter shaft and the expandable member, the sheath having a reinforced distal portion adapted to resist radial expansion of the expandable member. Claim 1 also has been amended to recite in part that moving the sheath axially toward the proximal end of the catheter shaft allows at least part of the expandable member to expand against the shuttle to cause the shuttle to radially expand while a remaining portion of the expandable member is constrained by the sheath, thus causing at least one of the plurality of stent segments to expand. Support for these amendments has already been

discussed above. Neither Chermoni, Fischell nor Shaknovich alone or in combination teach or suggest each and every element of the claimed invention.

As discussed above, Chermoni does not disclose a sheath and therefore Chermoni fails to teach or suggest a sheath having a reinforced distal portion adapted to resist radial expansion of the expandable member. Additionally, because Chermoni does not disclose a sheath, Chermoni also fails to teach or suggest that moving the sheath axially toward the proximal end of the catheter shaft allows at least part of the expandable member to expand against the shuttle to cause the shuttle to radially expand while a remaining portion of the expandable member is constrained by the sheath, thus causing at least one of the plurality of stent segments to expand.

Fischell discloses an integrated catheter system including a stent catheter and a balloon angioplasty catheter, and this has been discussed above. In Fischell's system the outer tube is fully retracted during radial expansion of the stent such that no part of the balloon is constrained from expansion by the outer tube (see Figs. 7E-7F). Because the outer tube does not constrain the balloon, Fischell fails to teach or suggest that moving the sheath axially toward the proximal end of the catheter shaft allows at least part of the expandable member to expand against the shuttle to cause the shuttle to radially expand while a remaining portion of the expandable member is constrained by the sheath, thus causing at least one of the plurality of stent segments to expand, as required by claim 3. Moreover, Fischell fails to teach or suggest that the outer tube is reinforced and there is no reason to reinforce Fischell's outer tube, thus Fischell also fails to teach or suggest that the sheath has a reinforced distal portion adapted to resist radial expansion of the expandable member, as also required by claim 3.

Shaknovich fails to provide the features missing from Chermoni and Fischell. Shaknovich discloses a stent delivery system including a tubular stent delivery shuttle having an expandable deployment segment onto which a stent can be mounted in a contracted configuration (Abstract). The deployment segment is expanded by a balloon catheter separate and distinct from the shuttle (Abstract). While Shaknovich discloses a guide catheter (see e.g. item 12 in Fig. 2), Shaknovich fails to teach or suggest that the guide catheter has a reinforced distal portion adapted to resist radial expansion of the expandable member. Because the purpose

of the guide catheter is to guide the stent delivery catheter to the treatment site, reinforcing a distal portion of the catheter would serve no purpose. Further, because such reinforcement frequently reduces the flexibility of a catheter, reinforcing the guide catheter of Shaknovich would likely make it less flexible and therefore less deliverable through the vessel, thereby detracting from its intended purpose. Furthermore, Shaknovich does not disclose using the guide catheter to constrain a portion of the expandable member, thus Shaknovich also fails to teach or suggest that moving the sheath axially toward the proximal end of the catheter shaft allows at least part of the expandable member to expand against the shuttle to cause the shuttle to radially expand while a remaining portion of the expandable member is constrained by the sheath, thus causing at least one of the plurality of stent segments to expand. In Shaknovich, each balloon is inflated in its entirety in order to expand the stent mounted over the balloon. If a portion of the balloon were constrained from expansion as in the present invention, the associated stent would be only partially expanded, not only rendering it inoperative to treat the diseased vessel but potentially blocking the vessel or making the stent impossible to remove from the vessel, thereby risking the life of the patient.

Because neither Chermoni, Fischell or Shaknovich alone or in combination teach each and every element of the claim, *prima facie* obviousness cannot be established under 35 U.S.C. § 103(a). Applicants respectfully request withdrawal of the 35 U.S.C. § 103(a) rejection and allowance of claim 3.

Claim 13 depends from independent base claim 11 which has been similarly amended as claim 1 above. Therefore, for at least the same reasons discussed above with respect to the rejection of claim 3, Applicants respectfully request withdrawal of the 35 U.S.C. § 103(a) rejection of claim 3 and allowance thereof.

Chermoni in view of Fischell and Martínez

Claim 19 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Chermoni in view of Fischell (U.S. Patent No. 5,639,274) and further in view of Martínez et al. (U.S. Patent No. 5,593,412). Such rejection is overcome for at least the following reasons.

Claim 19 includes the features recited in independent claim 11 which has been amended to recite in part an axially movable sheath disposed over at least part of the catheter shaft and the expandable member, the sheath having a reinforced distal portion adapted to resist radial expansion of the expandable member. Claim 11 also has been amended to recite in part that moving the sheath axially toward the proximal end of the catheter shaft exposes at least part of the expandable member, allowing it to expand against the shuttle to cause the shuttle to radially expand while a remaining portion of the expandable member is constrained by the sheath, causing at least one of the plurality of stent segments to expand. Support for these amendments has previously been discussed. Neither Chermoni, Fischell nor Martinez alone or in combination teach or suggest each and every element of the claim.

Amended claim 11 has already been distinguished from Chermoni which fails to teach or suggest a sheath. Claim 11 has also been distinguished from Fischell which fails to teach or suggest a sheath having a reinforced distal portion adapted to resist radial expansion of the expandable member, and claim 11 is further distinguished from Fischell because Fischell also fails to teach or suggest that moving the sheath axially toward the proximal end of the catheter shaft exposes at least part of the expandable member, allowing it to expand against the shuttle to cause the shuttle to radially expand while a remaining portion of the expandable member is constrained by the sheath, causing at least one of the plurality of stent segments to expand.

Martinez fails to provide the elements missing from Chermoni and Fischell. Martinez discloses a stent delivery apparatus having an elongate sheath which is constructed in a manner that permits the distal end portion to expand easily (Abstract). More specifically, Martinez discloses a sheath having slits on the distal end and that softens upon heating to facilitate passage of a stent through the sheath opening (col. 4, lines 53-67). Therefore, Martinez fails to teach or suggest a sheath having a reinforced distal portion adapted to resist radial expansion of the expandable member. Moreover, because Martinez advocates a soft, easy to open sheath tip, Martinez actually teaches away from a sheath having a reinforced distal portion, because reinforcing the sheath would make it more rigid and more difficult to open up to allow the stent to pass through. Therefore, there is no motivation or suggestion to modify Martinez's sheath with a reinforced section. Additionally, Martinez discloses that the sheath is retracted

fully away from the balloon during stent expansion (Fig. 5), thus Martinez also fails to teach or suggest that moving the sheath axially toward the proximal end of the catheter shaft exposes at least part of the expandable member, allowing it to expand against the shuttle to cause the shuttle to radially expand while a remaining portion of the expandable member is constrained by the sheath, causing at least one of the plurality of stent segments to expand. Also, in Martinez, the balloon is inflated in its entirety in order to expand the stent mounted on the balloon. No portion of the balloon can be constrained from expansion because the associated stent would be only partially expanded thereby rendering it inoperative to treat the diseased vessel and potentially blocking the vessel or making the stent impossible to remove from the vessel, which potentially endangers the patient.

Because neither Chermoni, Fischell or Martinez teach or suggest each and every element of claim 19, *prima facie* obviousness cannot be established under 35 U.S.C. § 103(a). Applicants respectfully request withdrawal of the 35 U.S.C. § 103(a) rejection and allowance of claim 19.

Chermoni in view of Fischell and Fernandez-Aceytuno

Claim 19 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Chermoni in view of Fischell '274 and further in view of Fernandez-Aceytuno (U.S. Patent No. 5,735,869). Such rejection is overcome for at least the following reasons.

Claim 19 includes the features recited in independent claim 11 which has been amended to recite in part an axially movable sheath disposed over at least part of the catheter shaft and the expandable member, the sheath having a reinforced distal portion adapted to resist radial expansion of the expandable member. Claim 11 also has been amended to recite in part that moving the sheath axially toward the proximal end of the catheter shaft exposes at least part of the expandable member, allowing it to expand against the shuttle to cause the shuttle to radially expand while a remaining portion of the expandable member is constrained by the sheath, causing at least one of the plurality of stent segments to expand. Support for these amendments has previously been discussed. Neither Chermoni, Fischell nor Fernandez-Aceytuno alone or in combination teach or suggest each and every element of the claim.

Amended claim 11 has already been distinguished from Chermoni which fails to teach or suggest a sheath. Claim 11 has also been distinguished from Fischell which fails to teach or suggest a sheath having a reinforced distal portion adapted to resist radial expansion of the expandable member and claim 11 was also distinguished from Fischell as not disclosing moving the sheath axially toward the proximal end of the catheter shaft exposes at least part of the expandable member, allowing it to expand against the shuttle to cause the shuttle to radially expand while a remaining portion of the expandable member is constrained by the sheath, causing at least one of the plurality of stent segments to expand.

Fernandez-Aceytuno fails to provide the elements missing from Chermoni and Fischell. Fernandez-Aceytuno discloses a stent delivery system for a balloon expandable stent including a balloon catheter with a tubular shaft and an elongated dilatation balloon (Abstract). A sleeve for preventing expansion of balloon segments is mounted on the tubular shaft with a distal end surrounding a portion of the proximal balloon end and a proximal end removably attached to a portion of the tubular shaft (Abstract). While the sleeve in Fernandez-Aceytuno prevents expansion of a balloon, Fernandez-Aceytuno fails to teach or suggest that the sleeve has a reinforced distal portion, as required by claim 19.

Therefore, because neither Chermoni, Fischell nor Fernandez-Aceytuno teach or suggest each and every element of the claimed invention, *prima facie* obviousness cannot be established for claim 19. Applicants respectfully request withdrawal of the 35 U.S.C. § 103(a) rejection and allowance of claim 19.

Chermoni in view of Fischell and Palermo

Claim 19 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Chermoni in view of Fischell '274 and further in view of Palermo (U.S. Patent No. 5,312,415). Such rejection is overcome for at least the following reasons.

Claim 19 depends from independent claim 11 and therefore includes the features recited in independent claim 11. Claim 11 has been amended to recite in part an axially movable sheath disposed over at least part of the catheter shaft and the expandable member, the sheath having a reinforced distal portion adapted to resist radial expansion of the expandable member.

Claim 11 also has been amended to recite in part that moving the sheath axially toward the proximal end of the catheter shaft exposes at least part of the expandable member, allowing it to expand against the shuttle to cause the shuttle to radially expand while a remaining portion of the expandable member is constrained by the sheath, causing at least one of the plurality of stent segments to expand. Support for these amendments has previously been discussed. Neither Chermoni, Fischell nor Palmero alone or in combination teach or suggest each and every element of the claim.

Amended claim 11 has already been distinguished from Chermoni which fails to teach or suggest a sheath. Claim 11 has also been distinguished from Fischell which fails to teach or suggest a sheath having a reinforced distal portion adapted to resist radial expansion of the expandable member and Fischell also fails to disclose moving the sheath axially toward the proximal end of the catheter shaft exposes at least part of the expandable member, allowing it to expand against the shuttle to cause the shuttle to radially expand while a remaining portion of the expandable member is constrained by the sheath, causing at least one of the plurality of stent segments to expand.

Palmero fails to provide the elements missing from Chermoni and Fischell. Palmero discloses a device for delivering embolic coils to a selected site (Abstract). The device comprises a sheath (e.g. item 102 in Fig. 1), yet Palmero fails to teach or suggest that his sheath has a reinforced distal portion adapted to resist radial expansion of the expandable member. Additionally, Palmero fails to disclose a balloon and therefore Palmero also fails to teach or suggest that moving the sheath axially toward the proximal end of the catheter shaft exposes at least part of the expandable member, allowing it to expand against the shuttle to cause the shuttle to radially expand while a remaining portion of the expandable member is constrained by the sheath, causing at least one of the plurality of stent segments to expand. Furthermore, because Palmero's sheath does not constrain a balloon from expansion, there is no motivation to modify the sheath to include a reinforced distal portion.

Because neither Chermoni, Fischell nor Palmero teach or suggest each and every element of the claimed invention, *prima facie* obviousness cannot be established for claim 19.

Applicants respectfully request withdrawal of the 35 U.S.C. § 103(a) rejection and allowance of claim 19.

Related Cases

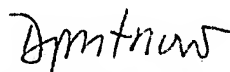
As a final matter, a Supplemental IDS will be submitted for consideration by the Examiner during prosecution of this application. Included in the Supplemental IDS is a listing of commonly-owned related cases. Each of these cases include disclosure related to prostheses and prostheses delivery systems. Applicants assume that the Examiner can access these but would be happy to provide copies of prosecution documents if requested.

CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 650-326-2400.

Respectfully submitted,


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